DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 22 1999

James L. Wilmer, Ph.D.
Senior Science Officer
Market America, Inc.
7605 Business Park Drive
Greensboro, North Carolina 27409

Dear Dr. Wilmer:

This is in response to your letter of November 15, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Market America, Inc. is making the following claims, among others, for the product **Glucosatrin**:

> "Helps control inflammation caused by cartilage breakdown"
> "Promotes the regeneration of damaged cartilage"
> "Reduces pain associated with cartilage loss"
> "Glucosatrin's active ingredients can help play a role in controlling inflammation and the pain that comes with it"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease, namely degenerative joint conditions. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Atlanta District Office, Office of Compliance, HFR-SE140

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (r/f, file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605 (Bowers)
HFV-228 (Benz)
GCF-1 (Dorsey, Barnett, Nickerson)
f/t:HFS-456:rjm:11/22/99:docname:68154.adv:disc42

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America's Most Powerful Business Opportunity

November 15, 1998

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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S. W.
Washington, D. C. 20204

Dear Sir/Madam:

I have enclosed notification forms which are intended to comply with Section 6 of the Dietary Supplement Health and Education Act of 1994 and Rule 21 C. F. R. §101.93. One dietary supplement called *Glucosatrin* is discussed. I have listed the structure-function statements found on product labels and associated support literature, and have identified the product ingredients that are the subject of the statements.

Thank you.

Sincerely,

James L. Wilmer

James L. Wilmer, Ph. D.
Senior Science Officer

Enclosures: 1 original and 2 copies

7605-A Business Park Drive • Greensboro, NC 27409
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NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND RULE 21 CFR §101.93

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Glucosatrin**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "A nutritional approach for healthy joints and cartilage."—bottle label.

Statement 2: "A nutritional approach for healthy joints and cartilage."—brochure.

Statement 3: "Helps control inflammation caused by cartilage breakdown."—brochure.

Statement 4: "Works with your body naturally."—brochure.

Statement 5: "Promotes the regeneration of damaged cartilage."—brochure.

Statement 6: "Reduces pain associated with cartilage loss."—brochure.

Statement 7: "Glucosatrin™ supplies glucosamine building blocks for the synthesis of cartilage and herbs for supporting our body's inflammatory response mechanisms."—brochure.

Statement 8: "When used at the same time as Glucosatrin™, complementary nutritional supplements are designed to strengthen and stabilize the collagen that is already in place in the joints."—brochure.

Statement 9: "Glucosatrin™, with its special glucosamine HCl/sulfate and herbal formula, provides an important nutritional approach for healthy joints and cartilage in one easy-to-take affordable dietary supplement."—brochure.

Statement 10: "Glucosatrin's active ingredients can help play a role in controlling inflammation and the pain that comes with it."—brochure.

Statement 11: "In addition, it [Glucosatrin™] can promote the regeneration of cartilage, including the tissue supporting the spinal disks."—brochure.

Statement 12: "Glucosatrin is designed to work with your body to support healthy inflammatory response mechanisms."—brochure.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

Statement Number	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
1-12	Glucosatrin™ is composed of: Glucosamine hydrochloride and glucosamine sulfate *Scutellaria baicalensis* root 2:1 extract Oleanolic acid (from *Ligustrum lucidum*) Boswellia resin (40% boswellic acids from *Boswellia serrata*) (Other ingredients: dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, stearic acid, silica, magnesium stearate, and pharmaceutical glaze)

The following identifies the brand name of each supplement for which a statement is made:

Statement Number(s)	Brand Name	Label or Labeling
1	Glucosatrin™	bottle label
2—12	Glucosatrin™	brochure

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: November 15, 1999 By: James L. Wilmer

James L. Wilmer, Ph. D.
Head, Scientific Affairs Dept.